IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

KEALANI DISTRIBUTION, LLC; UNITED STATES VAPING ASSOCIATION, INC; DIAMOND VAPOR LLC; JOHNNY COPPER LLC; SWT GLOBAL SUPPLY, INC.; CAROLINA VAPOR MILL LLC; CAROLINA VAPOR MILL WOODRUFF ROAD; and CVM3 LLC,	§	
Plaintiffs,	§	
	§	Civil Case No. 22-cv-856
v.	§	
FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs; and XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,	§	DECLARATORY AND INJUNCTIVE RELIEF REQUESTED
Defendants.	§	

COMPLAINT

Plaintiffs bring this action for declaratory and injunctive relief, and will show as follows:

INTRODUCTION

1. This is an action for declaratory and injunctive relief arising under the judicial review provision of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq*. Plaintiffs are small businesses engaged in the manufacture of bottled "e-liquids" (liquids used in "electronic nicotine delivery systems") and a trade association representing the interests of such businesses.

2. This lawsuit is brought because the Food and Drug Administration published a final rule, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, 86 Fed. Reg. 55300 *et seq.* (October 5, 2022) ("PMTA Final Rule"), setting out burdensome and costly requirements for applications ("PMTAs") seeking marketing authorization for Plaintiffs' products, in violation of the Regulatory Flexibility Act. The PMTA Final Rule was published in violation of the Act because FDA improperly certified that the Rule would not have a significant impact on a substantial number of small entities, such as Plaintiff manufacturers. 86 Fed. Reg. 55405. Contrary to the FDA's indefensible certification, the PMTA Final Rule implements statutory requirements in such a burdensome way that many manufacturers are unable to prepare an application at all, simply because of the cost and regulatory burdens involved. For those that *have* prepared marketing applications, or are in the process of doing so, the rule has forced them to substantially narrow the proportion of their products for which marketing approval is sought.

3. Plaintiffs request that the Court declare the FDA's certification to be erroneous, remand the PMTA Final Rule to the FDA, and preclude any enforcement of the PMTA requirements against small entities until FDA complies with its obligations under the Regulatory Flexibility Act.

JURISDICTION AND VENUE

4. This civil action arises under the Administrative Procedure Act and the Regulatory Flexibility Act. *See* 5 U.S.C. § 611(a). This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1331 (federal question jurisdiction). Declaratory relief is authorized by 28 U.S.C. § 2201, and injunctive relief by 28 U.S.C. § 2202 and Federal Rule of Civil Procedure 65.

5. Venue is proper under 28 U.S.C. § 1391(e)(1) because Plaintiff Kealani Distribution LLC resides in this district and division.

PARTIES

6. Plaintiff **United States Vaping Association (USVA)** is a trade association organized in accordance with Section 501(c)(6) of the Internal Revenue Code, with its principal place of business at 100 E. Whitestone Blvd., 148, Cedar Park, Texas 78613. USVA was organized in August 2019 to represent small-business vaping manufacturers and retail vape shops. The effects of the Deeming Rule (discussed below) were a primary motivation for organization of the USVA. With a focus on representing the needs of small-business vaping industry participants, the USVA furthers its mission by developing recommended industry best practices, assisting its members in efforts to prepare for and comply with the new regulatory environment, and engaging in litigation to further the interests of small businesses in the industry. The USVA has standing to bring this suit because (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. *United Food and Commercial Workers Union Local 751 v. Brown Group, Inc.*, 517 U.S. 544, 553 (1996) (quoting *Hunt v. Washington State Apple Advertising Com'n*, 432 U.S. 333, 432 (1977)).

7. Plaintiff **Kealani Distribution LLC** is a manufacturer of e-liquids with a principal place of business in Collin County, Texas, at 901 W Parker Rd., Ste. 121, Plano. Kealani submitted a PMTA for certain products manufactured with synthetic nicotine before the statutory deadline in April 2022. The burdensome requirements of the PMTA Final Rule are so costly that Kealani was forced to narrow the list of products for which it sought approval in such PMTA to only 10% of its product list.

8. Plaintiff **Diamond Vapor LLC** is a manufacturer of e-liquids with a principal place of business at 900 North Federal Hwy., Ste. 106, Hollywood, FL 33020. Diamond Vapor submitted a bundled PMTA in September 2020 (before the PMTA Final Rule was promulgated) for certain products manufactured with tobacco-derived nicotine (hereinafter, "traditional nicotine"). FDA denied that application with a marketing denial order ("denial order" or "MDO") in September 2021. Diamond Vapor filed a petition for review of such order in the Eleventh Circuit Court of Appeals. The Eleventh Circuit stayed FDA's denial order in February 2022, allowing Diamond Vapor to continue manufacturing its traditional nicotine products pending resolution of its petition for review. *Bidi Vapor LLC, et al. v. FDA*, No. 13340 (11th Cir. 2022). In August 2022, the Eleventh Circuit ruled for Diamond Vapor on the merits, vacating the FDA's denial order as to the traditional nicotine PMTA and remanding the application to FDA. *Bidi Vapor LLC v. FDA*, __ F.4th __, 2022 WL 3594073 (11th Cir. 2022). Diamond Vapor submitted a bundled PMTA for certain products manufactured with synthetic nicotine by the statutory deadline. That application remains pending. The burdensome requirements of the PMTA Rule imposed substantial costs for the preparation of such PMTA, and severely limit the proportion of Diamond Vapor's products that can be submitted to individual testing.

9. Plaintiff **Johnny Copper LLC** is a manufacturer of e-liquids with a principal place of business at 200A South Orange Ave., Green Cove Springs, FL 32043. Johnny Copper submitted a bundled PMTA in September 2020 (before the PMTA Final Rule was promulgated) for certain products manufactured with traditional nicotine. FDA denied that application with a marketing denial order in September 2021. Johnny Copper filed a petition for review of such order in the Eleventh Circuit Court of Appeals. The Eleventh Circuit stayed FDA's denial order in February 2022, allowing Johnny Copper to continue manufacturing its traditional nicotine products pending

resolution of its petition for review. *Bidi Vapor LLC, et al. v. FDA*, No. 13340 (11th Cir. 2022). In August 2022, the Eleventh Circuit ruled for Johnny Copper on the merits, vacating the FDA's denial order as to the traditional nicotine PMTA and remanding the application to FDA. *Bidi Vapor LLC v. FDA*, __ F.4th __, 2022 WL 3594073 (11th Cir. 2022). The burdensome requirements of the PMTA Final Rule are so costly that Johnny Copper is precluded from seeking approval for any additional products.

10. Plaintiff **SWT Global Supply, Inc. ("SWT")**, is a manufacturer of e-liquids with a principal place of business at 19871 Highway HH, Crocker, Missouri 65452. SWT submitted a bundled PMTA in September 2020 (before the PMTA Final Rule was promulgated) for certain products manufactured with traditional nicotine. FDA denied those applications with a marketing denial order in September 2021. SWT filed a petition for review of such order in the Fifth Circuit Court of Appeals. The Fifth Circuit stayed FDA's denial order in November 2021, allowing SWT to continue manufacturing the traditional nicotine products at issue pending resolution of its petition for review. *SWT Global Supply, Inc., et al. v. FDA*, No. 21-60762 (5th Cir. 2021). SWT's petition for review remains pending in the Fifth Circuit. SWT would seek approval for additional/new products, but the burdensome requirements of the PMTA Final Rule are so costly that SWT is precluded from seeking approval for any additional products.

11. Plaintiffs **Carolina Vapor Mill LLC**, **Carolina Vapor Mill Woodruff Road**, and **CVM3 LLC**, are related entities (referred to collectively herein as "Carolina Vapor Mill"), engaged in the manufacture of e-liquids, with a principal place of business at 1200 Woodruff Rd., C-5, Greenville, SC 29607. Carolina Vapor Mill submitted a bundled PMTA for certain products manufactured with synthetic nicotine in 2022. While that application remains pending, FDA has threatened to commence enforcement against Plaintiff's products that are the subject to the PMTA.

The burdensome requirements of the PMTA Final Rule are so costly that Carolina Vapor Mill's PMTA seeks approval only for a significantly narrowed list of its products.

12. Defendant Food and Drug Administration is an agency of the United States government within the Department of Health and Human Services, with an office at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993. The Secretary of Health and Human Services has purported to delegate to FDA the authority to administer the Tobacco Control Act.

13. Defendant Robert M. Califf, M.D., is Commissioner of Food and Drugs and is the senior official of the FDA. He is sued in his official capacity. Dr. Califf maintains an office at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

14. Xavier Becerra is Secretary of Health and Human Services and the official charged by law with administering the Act. He is sued in his official capacity. Secretary Becerra maintains an office at 200 Independence Avenue SW, Washington, D.C. 20201.

15. All Defendants are collectively referred to hereinafter as "FDA."

STATEMENT OF FACTS

The "Tobacco Control Act"

16. In 2009, Congress amended the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FD&C Act") by passing the Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1777 (2009) (the "Tobacco Control Act" or "TCA"), *codified at* 21 U.S.C. 387 *et seq*.[1] The Tobacco Control Act mandates that "[t]obacco products … shall be regulated by the Secretary [of Health and Human Services] under this subchapter and shall not be subject to the provisions of subchapter V," which governs "drugs" and "devices" separately. 21 U.S.C. § 387a.

[1] The TCA comprises subchapter IX of the Food, Drug, and Cosmetic Act (FDCA), which is codified in chapter 9 of title 21 of the United States Code.

17. "Tobacco product" is defined to mean:

> any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

21 U.S.C. § 321(rr)(1).

18. The terms "component," "part," and "accessory" are not further defined by statute.

19. While tobacco products fitting the statutory definition were extant in many and long-established forms when Congress enacted the TCA—including cigarettes, cigars, smokeless tobacco, and hookah—Congress did not choose to impose the Act's requirements on all such forms of tobacco products. Instead, Section 901 of the TCA provides that "[t]his chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter." *Id.*, *codified at* 21 U.S.C. § 387a(b).

20. "Roll-your-own tobacco" is defined to mean "any tobacco product which … is suitable for use and likely to be offered to, or purchased by, consumers as tobacco *for making cigarettes*." 21 U.S.C. § 387(15) (emphasis added).

21. Therefore, Congress itself imposed the TCA only upon cigarettes and cigarette tobacco, and "smokeless tobacco," which is limited to "any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity." *Id.* § 387(18). Left unregulated were all other forms of tobacco products, including products as the vapor products at issue here, as well as cigars and hookah.

22. While Congress itself declined to impose the TCA's requirements on anything other than cigarettes or "smokeless tobacco," it vested the Secretary of Health and Human Services with

the authority impose the Act on "any other tobacco products that the Secretary by regulation deems to be subject to [the TCA]." 21 U.S.C. § 387a(b).

23. The Secretary exercised that authority in 2016, issuing the Deeming Rule,[2] which applied the TCA to all products meeting the statutory definition of "tobacco product," including the vapor products at issue here. 21 Fed. Reg. 28,976.

24. The TCA imposes a variety of regulatory requirements on tobacco products subject to it. As particularly relevant here, the TCA prohibits the marketing of any covered "new tobacco product" without the FDA's approval, unless the product is grandfathered. *Id.* § 387j. None of the products at issue here fall under the grandfather provision, because they were not commercially marketed before February 15, 2007.

25. For products that are not grandfathered, there are two main pathways for FDA approval to market a "new tobacco product" covered by the TCA.

26. The less onerous pathway is to demonstrate that the new product is "substantially equivalent" to a product that was being commercially marketed in the United States on the February 2007 grandfather date. 21 U.S.C. § 387j(b). Substantial equivalence is demonstrated if the product "(i) has the same characteristics[3] of the predicate tobacco product; or (ii) has different characteristics and the information submitted [in the substantial equivalence report] contains information … that demonstrates that it is not appropriate to regulate the product … because the

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[2] *Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, No. FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016) ("Deeming Rule"). The Rule went into effect 90 days after its publication. 81 Fed. Reg. at 28,976.

[3] "Characteristics" means "the materials, ingredients, design, composition, heating source, or other features of a tobacco product." 21 U.S.C. § 387j(a)(3)(B).

product does not raise different questions of public health." *Id.* § 387j(a)(3)(A). If the FDA concludes that the new product is substantially equivalent to the predicate product, it must issue an order allowing the product to be commercially marketed. *Id.* § 387j(c). The "substantial equivalence" pathway was and is not available for Plaintiffs' products (or any e-liquids for vapor devices) because there were no such products being commercially marketed before February 2007.

27. Consequently, Plaintiffs must seek FDA approval through a "premarket tobacco application," referred to as a "PMTA."[4]

28. The TCA sets out certain categories of information that a PMTA must contain. 21 U.S.C. § 387j provides:

> (b) Application
>
> (1) Contents
>
> An application under this section shall contain--
>
> (A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;
>
> (B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;
>
> (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;
>
> (D) an identifying reference to any tobacco product standard under section 387g of this title which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;
>
> (E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

[4] *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry* at 1 (Jun. 2019), https://www.fda.gov/media/127853/download.

> (F) specimens of the labeling proposed to be used for such tobacco product; and
>
> (G) such other information relevant to the subject matter of the application as the Secretary may require.

29. The statute does not elaborate further on the content requirements for each identified category of information, but it does provide some broad guidelines of sorts for the FDA's action on an application. 21 U.S.C. § 387j provides, in relevant part:

> (c) Action on application
>
> …
>
> (2) Denial of application
>
> The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application *and any other information before the Secretary with respect to such tobacco product*, the Secretary finds that--
>
> (A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;
>
> (B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;
>
> (C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or
>
> (D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and there is a lack of adequate information to justify the deviation from such standard.
>
> …
>
> (4) Basis for finding
>
> For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account--
>
> (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
>
> (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.
>
> (5) Basis for action

> (A) Investigations
>
> For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, *when appropriate*, be determined on the basis of well-controlled investigations, which *may* include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.
>
> (B) *Other evidence*
>
> If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, *the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence*.

21 U.S.C. 387j(c) (emphasis added).

30. As will be shown in this case, one of the costliest requirements of the PMTA process—as implemented in the PMTA Final rule challenged here—is the requirement for reports of "health risk investigations" under subsection (2)(A). As reflected above, the statute vests broad discretion in the FDA to flesh out these requirements. When the FDA issued the Deeming Rule, it had not even begun to decide important issues, including the question of when it would be "appropriate" to require applicants to submit certain "investigations" of their own (including, *inter alia*, potential requirements for human clinical trials or other long term studies), or under what circumstances FDA might rely on its own studies or studies already in the public domain.

31. Nonetheless, the FDA undertook a preliminary analysis of the costs of preparing a PMTA at that time, which FDA expressly acknowledged was incomplete in relevant respects.

32. FDA acknowledged that the Deeming Rule's final regulatory impact analysis ("RIA") "accounted for the costs to comply with the format and content requirements of a PMTA *as described in the TCA*." PMTA Preliminary RIA at 22 (Sept. 24, 2019) (emphasis added).

33. As one illustrative example, in the discussion of potential "Human Studies," FDA spoke as if it expected applicants to be able to rely substantially on public information or 70 studies the FDA *itself* was conducting at the time. *See* Deeming Rule Final RIA at 149-50 (May 2016).

34. As another example, in discussing "market adjustment costs," FDA acknowledges that subjecting vapor product manufacturers to the PMTA requirement will cause many firms to exit the market to avoid the compliance costs. FDA predicted a mass exit of small manufacturers from the market, but said the scope of such "adjustment" was too uncertain to estimate at that time. Deeming Final RIA at 104-05.

35. Indeed, in one place, FDA expressly acknowledged the fact that it "cannot predict the costs or benefits of future rulemaking before the contents of the rules themselves have been established." Deeming Rule, Final RIA at 54.

36. The TCA generally requires the FDA to approve or deny a PMTA within 180 days. 21 U.S.C. § 387j(c)(1)(A), although the period may be extended to allow for certain necessary supplementation.

37. Failure to comply with the above-described provisions can result in a variety of serious consequences for manufacturers and retailers, including designation of one's products as misbranded or adulterated, *see* 21 U.S.C. §§ 387b, 387c, which in turn can trigger substantial civil penalties and imprisonment, 21 U.S.C. §§ 331, 333, as well as seizure of the offending products, 21 U.S.C. § 334.

38. FDA published the Deeming Rule in the Federal Register on May 10, 2016.

39. One of the immediate effects of the Deeming Rule was to effectively freeze the vapor market in place as of August 8, 2016 (the effective date of the rule). For any covered product that was already being commercially marketed as of August 8, 2016, FDA stated that it would

withhold enforcement until PMTAs could be submitted and reviewed according to a staggered set of deadlines announced in the Deeming Rule. While extant products could thus remain on the market during this compliance review period, no products not already commercially marketed as of August 8, 2016 could be offered unless a PMTA for such product was actually approved.[5]

FDA Delays Enforcement and PMTA Filing Requirements for Years After Deeming While Attempting to Settle on the "Rules of the Road" for Vapor PMTAs

40. Under the "compliance policy" announced at the time, PMTA submissions were originally required by August 8, 2018. 81 Fed. Reg. at 29009-29015.[6]

41. FDA emphasized that, as it gained experience regulating ENDS products, it expected to provide more guidance and regulations specifying what information an applicant could include in a PMTA to satisfy Section 910's standard of showing that marketing a given ENDS product would be "appropriate for the protection of the public health." *Id*. at 28997, 29012, 29051-52.

42. Along with the Deeming Rule, FDA published draft guidance for ENDS manufacturers titled "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Draft Guidance." FDA, Draft Guidance, Premarket Tobacco Product Applications for ENDS, 81 Fed. Reg. 28781 (May 10, 2016).

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[5] Application of the TCA to ENDS (and all other newly-deemed products) imposed other immediate restrictions upon the effective date of the Deeming Rule (August 8, 2016), including the required submission of ingredient listing, "manufacturer" registration and product listing, prohibition of the sale or distribution of products bearing 'modified risk' descriptions (such as 'light,' 'low,' or 'mild') without FDA approval (subject to a separate "Modified Risk" approval process), and a prohibition on distribution of free samples. *See* Deeming Rule, 81 Fed. Reg. at 28,976.

[6] FDA stated that ENDS products on the market as of August 8, 2016, would not be subject to FDA enforcement action for failure to submit a PMTA before the August 8, 2018, deadline. 81 Fed. Reg. at 28977-78, 29011.

43. FDA would go on to repeatedly confirm that it would publish further guidance and a formal "foundational rule" to provide the "rules of the road" so that vapor manufacturers could comply with the yet-to-be-determined PMTA filing requirements.

44. In late July 2017, FDA stated that it planned to issue foundational rules regarding PMTAs to "make the product review process more efficient, predictable, and transparent for manufacturers . . . . Among other things, the FDA intends to issue regulations outlining what information the agency expects to be included in [PMTAs]." *See* Press Release, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 27, 2017).

45. In August 2017, FDA issued guidance extending the compliance deadline for PMTA submissions from August 8, 2018, to August 8, 2022. *See* FDA, Guidance for Industry, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (August 10, 2017), at 8. While it postponed the deadline, this guidance did not provide any new guidelines or direction from FDA on the requirements for PMTAs or FDA's planned PMTA review process.

46. On November 3, 2017, then-FDA Commissioner Scott Gottlieb stated that "[t]he foundational regulations for the tobacco program were never put in place and so we're going to take the time to put those in place so we have a firm foundation from which to regulate." FDA Comm'r S. Gottlieb, Remarks at the National Press Club (Nov. 3, 2017).

47. By the end of 2017, FDA had advised stakeholders that it was pursuing a new comprehensive plan, that there would be new rules forthcoming, and that FDA would take the time necessary to get the process for PMTAs for ENDS products right.

48. On March 15, 2018, then-Commissioner Gottlieb stated:

> "For example, our plan demonstrates a greater awareness that nicotine, while highly addictive, is delivered through products on a continuum of risk, and that in order to successfully address cigarette addiction, we must make it possible for current adult smokers who still seek nicotine to get it from alternative and less harmful sources. To that end, the agency's regulation of both novel nicotine delivery products such as e-cigarettes and traditional tobacco products will encourage the innovation of less harmful products while still ensuring that all tobacco products are put through an appropriate series of regulatory gates to maximize any public health benefits and minimize their harms. This will be achieved through our ongoing regulatory work to develop several foundational rules, guidances, product standards and other regulations.
>
> . . . .
>
> Finally, we also plan to take new steps to make sure that our policies and processes for the regulation of tobacco products are efficient and predictable, and consistent with the mandate Congress gave us under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). We're committed to making sure that we have transparent regulatory policies and best practices in place to maximize our public health impact. To these ends, we plan to issue a series of foundational rules and guidance documents that will delineate key requirements of the regulatory process, such as the demonstration of substantial equivalence and the submission of applications for new tobacco products.[7]

49. In October 2018, FDA held a public meeting to "improve public understanding . . . on the process for the submission and review of [PMTAs]." Tobacco Product Application Review – A Public Meeting (October 22, 2018). In relaying the types of studies that could support a PMTA, an FDA representative stated: "No specific studies are required for a PMTA; it may be possible to support a marketing order for an ENDS product without conducting new nonclinical or clinical studies given other data sources can support the PMTA." Premarket Tobacco Product Application Content Overview: Iilun Murphy – OS/Division of Individual Health Science (October 23, 2018). FDA made similar statements at a public meeting held in 2019, describing reviewing a PMTA as a "[m]ulti-disciplinary approach," and citing numerous factors that must be

[7] *Statement from FDA Comm'r S. Gottlieb, M.D., on pivotal public health step to dramatically reduce smoking rates by lowering nicotine in combustible cigarettes to minimally or non-addictive levels* (Mar. 15, 2018) (emphasis added).

considered for determining whether a product is appropriate for protection of the public health, including health risks and marketing plans. *See* Deemed Tobacco Product Applications – A Public Meeting (October 28- 29, 2019).

The PMTA Rule Challenged Here

50. FDA finally published the proposed final PMTA rule on September 25, 2019.

51. With the proposed rule, FDA published a preliminary regulatory impact analysis and initial regulatory flexibility analysis ("PMTA Rule Preliminary RIA"). In that document, FDA proposed to certify that the PMTA Rule "would not have a significant economic impact on a substantial number of small entities." PMTA Rule Preliminary RIA at 6. Despite the fact that this new Rule takes over 100 pages to describe the PMTA requirements for vapor products, by FDA's rationale, this new Rule would actually "generate net benefits or negligible costs for most affected small entities." *Id.* FDA reasoned that it had "already included the costs to submit and review PMTAs for deemed tobacco products in the final [RIA] for the Deeming Rule" in 2016. *Id.* at 7.

52. As authorized by statute, the Small Business Administration's Office of Advocacy filed official comments objecting that FDA's proposed certification that the PMTA Rule would have no significant impact on a substantial number of small entities lacked an adequate factual basis.

53. Specifically, Advocacy's letter objected that the certification "improperly assumes that the compliance costs of the proposed rule's requirements for deemed products are due to the agency's 2016 rule," rather than to the PMTA Final Rule, which finally explained FDA's interpretation and implementation of the baseline statutory guidelines.

54. Notwithstanding Advocacy's objection, FDA published the PMTA Final Rule in the Federal Register on October 5, 2021, certifying no significant impact on a substantial number

of small entities. 86 Fed. Reg. 55300, 55405-06. Consequently, FDA did not perform or publish any final regulatory impact analysis or regulatory flexibility analysis with the PMTA Final Rule, and therefore did not conduct any analysis of potential alternatives or modifications to the rule that could lessen the burden on small entities while still satisfying the statutory requirements.

CLAIM FOR RELIEF

The PMTA Final Rule Was Promulgated in Violation of the Regulatory Flexibility Act

55. Plaintiffs re-allege and incorporate by reference all of the allegations contained in the preceding paragraphs.

56. The Regulatory Flexibility Act requires any federal agency to undertake certain specific steps in consideration of the impact of a proposed rule that would affect a substantial number of small entities, including analysis of potential alternatives to the regulation that would satisfy the statutory requirements without imposing unnecessary burdens on small businesses. 5 U.S.C. § 604(a).

57. This obligation can only be avoided "if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." *Id.* § 605(b).

58. Plaintiff manufacturers are all small entities for purposes of the regulation because they all have fewer than 1,500 employees. Plaintiff USVA is a trade association that represents the interests of many manufacturers and retail members in the industry. All Plaintiffs are injured by the PMTA Final Rule as alleged above. USVA also has many additional members who are also injured by the PMTA Final Rule for the same reasons.

59. Plaintiffs timely challenge the PMTA Final Rule.

60. FDA's certification of no significant impact on a substantial number of small entities is erroneous on its face. Under established principles of administrative law, FDA has broad authority to flesh out the otherwise bare-bones content- and standard-of-review provisions governing PMTAs. FDA's analysis of the costs to vapor-industry firms for preparation and submission of PMTAs was expressly conditional and caveated, as it must have been, as it was prepared before FDA had even begun to promulgate specific requirements.

61. FDA—for years after extending its authority over the vapor industry in 2016—acknowledged that the "rules of the road" for vapor industry PMTAs had not yet been determined. This was the very reason FDA repeatedly extended compliance deadlines.

62. FDA could have interpreted the statutory PMTA guidelines in various ways, and it chose to regulate in a manner that imposes very burdensome requirements on all applicants.

63. FDA itself admitted in the Deeming Rule Final RIA that it could not estimate the costs of rules that had not yet been promulgated; yet, when it issued the PMTA Final Rule, it adverted to the analysis performed years earlier, before any proposed rule was even devised.

64. As another example, FDA's certification is premised on ignoring the PMTA Final Rule's impact in forcing many small entities out of the market altogether, simply as a result of the compliance costs. FDA admitted in 2016 that it could not provide a reliable estimate of the number of small firms that would exit, but when the PMTA Final Rule was issued, FDA ignored the impact on such entities entirely, by considering only the regulatory cost to those firms that actually file applications.

65. This was erroneous. The FDA Commissioner in 2017 expressly acknowledged that because the FDA's Center for Tobacco Products was so new, with scant experience regulating

vapor products, the agency had no "firm foundation on which to regulate," and had not set out the "rules of the road" for vapor PMTAs.

66. The PMTA Final Rule has a significant impact on a substantial number of small entities. FDA's Final Rule imposes a significant impact on every small entity, preventing many from applying all, and narrowing the scope of the applications filed by those firms who can afford to submit a PMTA. FDA did not have to regulate in the manner that it did, and its certification wholly ignores the economic impact of the choices it made in devising the PMTA Final Rule (instead simply relying on its forecast from 2016, based on the bare-bones provisions of the statute itself). FDA's certification is erroneous.

67. Plaintiffs thus seek a declaration that the PMTA Final Rule was issued in violation of the Regulatory Flexibility Act, and an order vacating the Rule until FDA complies with its obligations under the Act.

PRAYER

Wherefore, Plaintiffs pray for relief as follows:

1. Declare the PMTA Final Rule in violation of the Regulatory Flexibility Act;
2. Remand the PMTA Final Rule to the FDA; and
3. Enjoin Defendants and any other agency or employee acting on behalf of the United States from enforcing the PMTA Final Rule against the individual Plaintiffs or any members of the USVA, and to take such actions as are necessary and proper to remedy their violations deriving from any such actual or attempted enforcement; and
4. Award Plaintiffs their reasonable attorney's fees and costs, and grant such other relief as the Court may deem just and proper.

Respectfully submitted,

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